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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,964	03/25/2004	Xiang-Jin Meng	AM100878-P1	7042

7590 03/15/2007

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,964	MENG ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,15,16,18-28,32,35 and 38* is/are pending in the application.

4a) Of the above claim(s) *23-28* is/are withdrawn from consideration.

5)☒ Claim(s) *1-10,32,35 and 38* is/are allowed.

6)☒ Claim(s) *15,16 and 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 July 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed December 22, 2006 is acknowledged and entered. Claims 1-10, 15, 16, 18-28, 32, 35 and 38 are pending. Claims 23-28 remain withdrawn from consideration, being drawn to non-elected subject matter. Claims 1-10, 15, 16, 18-22, 32, 35 and 38 are under examination.

Claims Summary

2. The claims are drawn to a viral vaccine comprising a carrier and an immunogenic amount of a member selected from the group consisting of:

a) a chimeric nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 2 or its complementary strand;

b) a biologically functional plasmid or viral vector containing a chimeric nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 2 or its complementary strand; and

c) an avirulent, infectious chimeric porcine circovirus made from a chimeric nucleic acid molecule of PCV1-2.

SEQ ID NO: is the full-length DNA sequence of the cloned chimeric PCV1-2 DNA). In another embodiment, the vaccine contains live chimeric porcine circovirus. Also claimed is a method of immunizing a pig against viral infection or postweaning multisystemic wasting syndrome (PMWS) caused by PCV2 comprising administering to the pig the vaccine. The vaccine is administered via a variety of routes.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15, 16 and 18-22 remain rejected under 35 U.S.C. 112, first paragraph. As asserted previously, the specification enables the inhibition of viral infection and prevention of PWMS with the PCV1-2 construct wherein the ORF2 capsid gene from PCV1 is replaced with the ORF2 capsid gene of the PCV2 (herein referred to as "the PCV1-2 capsid construct"). However, the specification does not reasonably provide enablement for immunizing against viral infection and PWMS with the PCV1-2 construct wherein any ORF from PCV1 is replaced with any ORF from PCV2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The particular embodiments that are not enabled are represented by claim 15(c) (the avirulent, infectious chimeric porcine circovirus does not require the presence of PCV2 capsid in the PCV1-2 construct), claims 18 and 20 (the live chimeric porcine circovirus does not require the presence of PCV2 capsid), and respective dependent claims thereof.

With regard to the PCV1-2 capsid construct, the relevant non-patent literature and the specification demonstrates protective immunity against wild-type PCV2 infection (Fenaux *et al.*, *Journal of Virology*, 2004, 78(12):6279-6303). However, the swapping of any ORF other than ORF2 (capsid) has not been shown, nor has such a construct been indicated as protective against PCV2 infection. The specification does not disclose the construction of any other PCV1-2 chimeric virus (or DNA clone) or challenge experiments. Vaccination (prevention) efficacy

requires challenge experiments in acceptable animal models. Applicant has demonstrated efficacy for one construct (PCV1-2 capsid), however, this single construct is not representative of all of the other PCV1-2 embodiments encompassed by the claims. No other open reading frames have been indicated as suitable for swapping such that protective immunity is achieved. Given the breadth of the claims, the data provided in the specification, the state of the art, the lack of guidance relating to non-PCV1-2 capsid constructs, and lack of challenge experiments, the specification is not enabling for the full breadth of the claimed embodiments.

Conclusion

4. Claims 1-10, 32, 35 and 38 are allowable.**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 3/12/07

STACY B. CHEN
PRIMARY EXAMINER